

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

re Application of:

Richard A. COUCH et al.

Serial No.: 10/774,697

Group Art Unit: 1614

Filed: February 10, 2004

Examiner: Unassigned

For: ENANTIOMERIC AMPHETAMINE COMPOSITIONS

# INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

#### Timing and Fees

$\boxtimes$	Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this inform disclosure statement is filed:					
			three months of the filing date of a national application other than a CPA $\S$ 1.53(d);			
			three months of the actual filing date of the national phase of a PCT ation; OR			
	$\boxtimes$	before RCE).	the mailing of a first substantive office action (including after filing of an			
			.R. § 1.97(c), this information disclosure statement is filed after the periods 7 C.F.R. § 1.97(b), but before the mailing date of:			
			a final rejection under 37 C.F.R. 1.113;			
			termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR			
			a notice of allowance under 37 C.F.R. § 1.311; and			

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		is acco	mpanied by:
			the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR
			a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).
			R. § 1.97(d), this information disclosure statement is filed after the mailing lowing actions which have not been withdrawn:
			a final action under 37 C.F.R. § 1.113;
			termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
			a notice of allowance under 37 C.F.R. § 1.311;
	AND i	s filed o	on or before payment of the issue fee; AND is accompanied by:
			the statement as specified in 37 C.F.R. $\S$ 1.97(e) as set forth below, and the fee of \$180.00 under 37 C.F.R. $\S$ 1.17(p).
Statem	nents Ur	nder 37	C.F.R. 1.97(e)
			Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
			No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.
Cited	Materia	<u>ls</u>	
		ancesto	of materials listed but not attached were cited in benefit (35 U.S.C. § 120) or application Serial No, on Form 892 by the Examiner and/or Form by the applicant; see 37 C.F.R. § 1.98(d).
		•	of materials listed but not attached were cited in an international search dated July 16, 2004.
	$\boxtimes$	Copies	s of the materials listed are attached (except for the foregoing).

	$\boxtimes$	An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).
[		A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:
		<ul> <li>X = document of particular relevance when it is taken alone</li> <li>Y = document of particular relevance when it is combined with another such document</li> <li>A = document defining the general state of the art</li> <li>O = non-written disclosure</li> <li>P = intercalated document</li> </ul>
		<ul> <li>T = document cited to understand the theory or principle underlying the invention</li> <li>E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date</li> <li>D = cited in the application</li> <li>L = cited for another reason</li> </ul>
[		& = publication of member of same patent family  Translation of other relevant information on foreign search report
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		ees Due (If Any): ck for \$ covering the fee identified above is attached.
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Non-English Language References

 $\boxtimes$ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,

Anthony J. Zelano, Reg. No. 27,969
Attorney for Application

Attorney for Applicants

MILLEN, WHITE, ZELANO & BRANIGAN, P.C. Arlington Courthouse Plaza ! 2200 Clarendon Blvd. Suite 1400 Arlington, Virginia 22201 Telephone: (703) 243-6333 Facsimile: (703) 243-6410

Attorney Docket No.: PHARMA-0148

Date: September 13, 2004

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February 10, 2004

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Application Number

Filing Date

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

TEMENT BY APPLICANT				First Named Inventor	Richard A. COUCH et al		
				Group Art Unit	1615		
	(use as many she	ets as	necessary)	Examiner Name	Unassigned		
_	1	of	2	Attorney Docket Number	PHARMA-0148		

	U.S. PATENT DOCUMENTS								
Examiner Initials *	Cite No.1	U.S. Patent Document  Kind Code <sup>2</sup> Number ( <i>if known</i> )		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document  MM-DD-YYYY				
	A1	2002/0058061 A1		Kamal K. MIDHA et al.	05/16/2002				
		70 . Mr. 700 W. W. W. V							
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	FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No.1	Office <sup>3</sup>	Foreign Patent Docum		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T⁵	
	B1	wo	2002/039998 A3		PCT	05/23/2002			
	B2	wo	00/23055		PCT	04/27/2000			
	В3	wo	03/092661 A1		PCT	11/13/2003			
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Examiner Name	Unassigned				
Attorney Docket Number	PHARMA-0148	フ			

	NON PATENT LITERATURE DOCUMENTS						
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2				
	C1	L. EUGENE ARNOLD et al., Levoamphetamine and Dextroamphetamine: Comparative Efficacy in the Hyperkinetic Syndrome, Assessment by Target Symptoms, Arch Gen Psychiat, Vol. 27, December 1972, pages 816-822	·				
	C2	L. EUGENE ARNOLD et al., Levoamphetamine and Dextroamphetamine: Differential Effect on Aggression and Hyperkinesis in Children and Dogs, Am J Psychiatry 130:2, February 1973, pages 165-170					
	СЗ	SIMON J. TULLOCH, et al., SLI381 (Adderall XR), a Two-Component, Extended-Release Formulation of Mixed Amphetamine Salts: Bioavailability of Three Test Formulations and Comparison of Fasted, Fed, and Sprinkled Administration, Pharmacotheraphy, Vol. 22, Number 11, 2002, pages 1405-1415					
	C4	KENNERLY S. PATRICK et al., Pharmacology of Methylphenidate, Amphetamine Enantiomers and Pemoline in Attention-Deficit Hyperactivity Disorder, Human Psychopharmacology, Vol. 12, pages 527-546 (1997)					
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